

### Remarks

Applicants appreciate the Examiner's helpful comments regarding the amendment needed to the Abstract and regarding the claim objections. Applicants have made each recommended change, but added no new subject matter. Those objections are now moot.

#### Response to the Rejection under 35 U.S.C. §101

The Examiner has rejected claims 1-21 and 25-30 under 35 U.S.C. §101 as being directed to non-statutory subject matter. However, in light of the Examiner's comments, claims 1 and 17 (and hence the claims dependent thereon), and claims 25-30 have been amended accordingly to demonstrate the production of a "useful, concrete and tangible result." The rejection is, therefore moot, and Applicants ask that it be withdrawn.

#### Response to the Rejection under 35 U.S.C. §112, second paragraph.

The Examiner has rejected claims 11-15 under 35 U.S.C. §112, second paragraph as being indefinite. However, in light of the Examiner's comments, claim 10, upon which claim 11 depends, has been amended to depend on claim 1, rather than on claim 4. The rejection is, therefore moot, and Applicants ask that it be withdrawn.

#### Response to the Rejection under 35 U.S.C. §102(a).

The Examiner has rejected claims 1-21 and 25-30 under 35 U.S.C. §102(a) as anticipated by Gomberg *et al.* (*Comp. Vision and Image Understanding* 86:171-190 (June 2002)). In making this rejection, the Examiner notes that the rule states that "[a] person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent. However, that is not the situation for this invention, as will be shown below.

Bryon R. Gomberg was a graduate student in Dr. Wehrli's and Dr. Saha's laboratory at the time of the invention. In his doctoral work, he was developing specific virtual bone biopsy applications for the previously conceived fuzzy distance transform invention of Drs. Saha and Wehrli, - - not the other way around as suggested by the Examiner. In other words, first the invention presently claimed by Applicants was established at a date prior to Gomberg's work, and then subsequently Gomberg developed the virtual bone biopsy application of that work.

The reference cited by the Examiner is misrepresented. It is not a manuscript on which

Gomberg is a lead author, nor is its publication date June 2002. The correct citation is, as noted in Applicants' IDS at item number 32, is Saha *et al.*, "Fuzzy distance transform: Theory, algorithms and applications," *Computer Vision and Image Understanding* 86:171-190 (November 27, 2002). The publication date was confirmed in writing by the editors of the journal. Thus, disclosures in the cited reference that are referred to by the Examiner in this Action, such as the disclosure of the dynamic programming-based algorithm to compute fuzzy distance transform by means of a plurality of points, is not a disclosure of Gomberg's own work. Rather, it is, in fact, a disclosure of the work presently set forth by the inventors in the present invention, upon which Gomberg relied to substantiate and support his own work relating to a virtual bone biopsy method.

Applicants' invention was first filed as a provisional application (US 60/431,129) on December 5, 2002. The provisional filing contained a manuscript, which was subsequently published as Saha *et al.*, "Fuzzy distance transform: Theory, algorithms and applications," *Computer Vision and Image Understanding* 86:171-190 (November 27, 2002)), although the title was changed from the title used on the manuscript submitted as the provisional filing. Nevertheless, the information contained in the provisional remained the same as in the published paper.

The case law and MPEP 706.02(a) state that "an Applicant's own work, even though publicly disclosed prior to his application, may not be used against him as a reference, absent the existence of a time bar to his application. *In re DeBaun*, 214 USPQ 933, 935 (CCPA 1982). The time bar referred to is the 1-year time bar set forth in 35 U.S.C. §102(b) (the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States). Consequently, the case law states that:

One's own work is not prior art under §102(a), even though it has been disclosed to the public in a manner or form which otherwise would fall under §102(a). Disclosure to the public of one's own work constitutes a bar to the grant of a patent claiming the subject matter so disclosed (or subject matter obvious therefrom) only when the disclosure occurred more than one year prior to the date of the application, that is, when the disclosure creates a one year time bar under §102(b). *In re Katz*, 215 USPQ 14, 17 (CCPA 1982).

This interpretation is reiterated in MPEP 706.02(c), which states that:

If the activity is by an entity other than the inventors or assignee, such as sale by another, manufacture by another or disclosure of the invention by applicant to another then both 35 U.S.C. 102(a) and (b) may be applicable. If the evidence only points to knowledge within the year prior to the effective filing date then 35 U.S.C. 102(a) applies. However, no rejection under 35 U.S.C. 102(a) should be made if there is evidence that applicant made the invention and only disclosed it to others within the year prior to the effective filing date.

Thus, no 102(a) rejection should have been made since the publication date of the cited article only one week before the filing of the provisional application, is certainly less than at least 1-year before Applicants' effective filing date of December 2002. The MPEP further indicates in section 706.02 that one way Applicants can overcome a 102(a) rejection is with the filing of a Declaration under 37 CFR 1.131 showing prior invention, if as is the present situation, the reference is not a U.S. patent or a U.S. patent application publication claiming the same patentable invention as defined in 37 C.F.R. 41.203(a). Consequently, Applicants could file such an affidavit establishing that their invention was invented prior to the cited Gomberg report. But since the publication date of the cited reference is less than a year before Applicants' effective filing date, and it is the inventors' own work on which a graduate student under their direction was named as an author, but not an inventor, a Declaration is not believed to be necessary.

Accordingly, it is argued that the cited Gomberg paper is not an appropriate "prior art" reference under either 102(a) or 102(b) against Applicants' invention. If the Examiner requires the filing of a Declaration under 37 CFR 1.131 showing prior invention by the inventors, Applicants will submit same. Otherwise, Applicants respectfully ask that the rejection under 35 U.S.C. §102(a) be reconsidered and withdrawn, since the cited reference is not permissible "prior art" in this case.

As to the references by the Examiner to 35 U.S.C. 112, sixth paragraph, Applicants cannot find a reference to a specific rejection based upon that statute. Accordingly Applicants cannot reply to such a reference until additional information is provided.

#### Response to the Rejection under 35 USC §103(a).

The Examiner has rejected claims 22-24 under 35 USC § 103(a) as unpatentable over Gomberg ("Fuzzy distance transform: Theory, algorithms and applications") in view of the Gomberg Doctoral Dissertation ("*In vivo* magnetic resonance based virtual bone biopsy"). In making this rejection, the Examiner points out that the teachings of Gomberg, while discussed above, "fails to disclose of fairly suggest selecting a therapy based on the diagnosis or

evaluation.”

However, there is a far greater problem with regard to the cited references, in that the cited paper is not by Gomberg *et al.* as suggested. To the contrary, the cited paper is by the inventors Saha and Wehrli, and as discussed above, Gomberg was merely a graduate student named on the paper for his work conducted under the direction of the inventors.

The manuscript represents the inventors own work, in which Gomberg was named as an author, but not as an inventor, since he operated under the direction, instruction and guidance of the inventors. Nevertheless, the cited manuscript is not prior art to the present US invention since it was published only a couple of weeks before the filing of the provisional application containing essentially the same information, meaning that the publication occurred well within the 1-year grace period before publications may be considered to be prior art.. Accordingly, the cited “Saha” reference (not Gomberg reference) cannot be used in an effort to fill-in the gaps left by the other publication cited by the Examiner.

The cited Gomberg Dissertation focused on the virtual bone biopsy, which is but one specific application of the fuzzy distance transform of the present invention. It does discuss the progression and regression of bone disease in a subject, but such discussion is meaningless without the underlying Saha/Wehrli invention of Applicants’ present application. The Gomberg Dissertation is also a 2002 publication, meaning that it could not have been published more than 1 year before Applicants’ effective filing date. So, it too, is not acceptable “prior art” with regard to Applicants’ present invention.

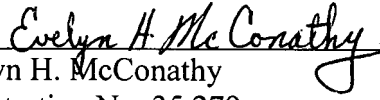
As noted above, since the publication associated with Applicants’ invention is not permissible “prior art,” the Gomberg Dissertation cannot be combined with the cited publication. Even if permissible, which it is not, the Gomberg Dissertation regarding virtual bone biopsy, alone without Applicants’ invention set forth in the cited combined reference, fails to disclose the subject matter of Applicants claims 22-24. This is not surprising, since Gomberg’s Dissertation is an extension of Applicants’ invention – but it is not “prior art” to Applicants’ invention. As a result, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

The remaining references cited by the Examiner are described as for reference purposes only, upon which no rejection was based, and none needs to be presently answered.

Applicants assert that all pending claims are in condition for allowance. Consequently, Applicants respectfully requests that allowance be granted at the earliest date possible. Should the Examiner have any questions or comments regarding Applicants' Response, the Examiner is asked to contact Applicants' undersigned representative at (215) 772-7550.

Respectfully submitted,

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